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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/177,814 10/23/98 GILTON

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EXAMINER

HM12/0216

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ART UNIT

PAPER NUMBER

1641

DATE MAILED:

02/16/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/177,814

Applicant(s)

GILTON, TERRY L.

Examiner

Gailene R. Gabel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2000.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1.3-11, 13-44, 46, 48-64, 66-74 and 105-107 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1.3-11, 13-44, 46, 48-64, 66-74 and 105-107 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 14) ☐ Notice of References Cited (PTO-892)
- 15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13.

- 17) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☐ Other: _____.

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DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response filed 8/29/00 in Paper No. 12 is acknowledged and has been entered. Claims 1, 3-7, 9-11, 13-15, 18-19, 21-22, 25, 29-30, 32-34, 39-42, 46, 48-52, 56-57, 61, 64, 66, and 71-72 have been amended. Claims 12, 45, and 47 have been cancelled without prejudice. Accordingly, claims 1, 3-11, 13-44, 46, 48-64, 66-74 and 105-107 are pending and under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 3-7, 9-11, 13-15, 18-19, 21-22, 25, 29, and 61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in reciting "associated with" because it is unclear what is encompassed by the term "associated" as used in the claim.

Claim 61 appears redundant in reciting "along a distance of at least one of said at least one sample column".

Claim R ejections - 35 USC § 102

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. The rejection of claim 12 under 35 U.S.C. 102(b) as being clearly anticipated by Isaka et al. (US 5,482,598) is now moot in light of Applicant's cancellation of the claim.

4. In light of Applicant's amendment and argument, the rejection of 1, 3-4, 7-9, 18-20, 25-26, 29-32, 34-35, 38-39, 50-52, 56, 64, 66, 69, 71, and 73 under 35 U.S.C. 102(b) as being *clearly* anticipated by Isaka et al. (US 5,482,598) is, hereby, withdrawn.

5. Alternatively, claims 1, 3-4, 7-9, 18-20, 25-26, 29-32, 34-35, 38-39, 50-52, 56, 64, 66, 69, 71, and 73 are rejected under 35 U.S.C. 102(b) as being *inherently* anticipated by Isaka et al. (US 5,482,598) for reasons of record. Isaka et al. has been thoroughly discussed in Paper No. 11.

Specifically, Isaka et al. teach incorporation of a sealing element (cover) consisting of a single-crystal silicon film on the silicon substrate on which the matrix is formed (see column 5, lines 38-49). Further, Isaka teaches that in forming a matrix on the semiconductor substrate by forming a mask, any number of desired patterns, i.e. differing lengths, linear, circular, on a surface of the semiconductor substrate can be created; just as any number of channels, i.e. two channels or columns, may be inherently disposed onto the microchannel element. For that reason, it is viewed that the claims, as amended, are inherently anticipated by Isaka.

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6. In light of Applicant's amendment and argument, the rejection of claims 1, 18, 22-24, 30, and 42 under 35 U.S.C. 102(e) as being clearly anticipated by Northrup et al. (US 5,882,496) is, hereby, withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The rejection of claims 45 and 47 under 35 U.S.C. 103(a) as being unpatentable over Isaka et al. (US 5,482,598) or if necessary, Northrup et al. (US 5,882,496) in view of Turner et al. (US 5,885,869) and in further view of Sunzeri (US 5,536,382) and Swedberg et al. (US 5,571,410) is withdrawn in light of Applicant's cancellation of the claims.

8. Claims 14-15, 16-17, 21, 40-41, 43-44, 54-55, and 70 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Isaka et al. (US 5,482,598) in view of Miura et al. (US 5,132,012) for reasons of record.

9. Claims 13, 21, 41, 53, and 70 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Isaka et al. (US 5,482,598) in view of Wang et al. (US 5,663,488) for reasons of record.

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10. Claims 33, 74, and 105-107 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Isaka et al. (US 5,482,598) in view of Turner et al. (US 5,885,869) for reasons of record.

11. Claims 5-6, 10-11, 27-28, 36-38, 46, 48-49, 57-63, 67-68, and 72 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Isaka et al. (US 5,482,598) or if necessary, Northrup et al. (US 5,882,496) in view of Turner et al. (US 5,885,869) and in further view of Sunzeri (US 5,536,382) and Swedberg et al. (US 5,571,410) for reasons of record.

New Grounds of Rejection

12. Claims 22-24, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isaka et al. (US 5,482,598) in view of Northrup et al. (US 5,882,496).

Isaka has been discussed in Paper No. 11. Specifically, Isaka et al. disclose a chromatography apparatus which includes a semiconductor substrate and a matrix (microchannel) which extends across the substrate wherein the matrix is formed with a desired pattern, i.e. linear, circular, on the semiconductor substrate by incorporating a porosity thereon in order to create a porous portion with increased pore size and extended branching of the pores on the semiconductor surface (see Abstract and column 1, lines 35-46). The length of the matrix channel is not limited although its length is preferably larger than its diameter (see column 2, lines 18-25). The porosity is preferably 10-90% (see column 2, lines 60-63). Optimal pore size and pore shape can

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be achieved in accordance with the substance to be separated and measured, i.e. selecting the type and concentration of a dopant (see column 3, lines 35-42). The separation makes use of the difference in flow rate between gases and liquids or in reactions (enzyme reaction) involving capture substrate (absorptivity involving immobilized enzyme) (see column 3, lines 1-14 and 50-54). In the device, an inlet port of the apparatus is coupled to a pump (migration facilitator) into the porous channel to identify difference in elution time between two liquids using differential refractometer (see column 5, lines 17-29). Isaka et al. also disclose an ion column detector, i.e. absorption detector on the device (see column 3, lines 16-24). Finally, Isaka et al. teach incorporation of a sealing element (cover) consisting of a single-crystal silicon film on the silicon substrate on which the matrix is formed (see column 5, lines 38-49).

Isaka et al. differ in failing to disclose a migration facilitator comprising a first electrode and a second electrode adjacent to a first and second end of the porous regions respectively.

Northrup et al. has been discussed in Paper No. 11. Specifically, Northrup et al. disclose fabrication and use of porous silicon structures to increase surface area of miniaturized electrophoresis devices and filtering or control flow devices (see Abstract). Northrup et al. disclose electrodes disposed within or adjacent the porous channels in order to control flow of electrically charged biochemical species such as in electrophoresis (see column 5, lines 21-67). Figure 3 illustrates porous silicon embodiment on a controlled flow interface device. Figure 8 illustrates a porous silicon

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electrophoresis device. A negative electrode is formed at one end (inlet) of the porous silicon column and a positive electrode is formed at an opposite end (outlet) of porous silicon columns, thereby forming microelectrophoresis channels (see column 7, lines 38-50).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to substitute the migration facilitator taught by Isaka with that taught by Northrup because Northrup specifically taught that electrodes can be applied into porous channels on microchannel devices to control flow such as in electrophoresis. One of ordinary skill in the art at the time of the instant invention would have been motivated to incorporate electrophoretic capability such as taught by Northrup into the microchannel device taught by Isaka because it allows for better control of flow for electrically charged biochemical species during separation.

Response to Arguments

13. Applicant's arguments with respect to 1, 3-11, 13-44, 46, 48-64, 66-74 and 105-107 have been considered but are not persuasive.

14. a) Applicant argues that Isaka does not anticipate the instant invention because Isaka lacks disclosure of more than one matrix and of at least two porous regions that extend partially across a substrate. Further Applicant argues that Isaka fails to disclose a detector fabricated on the substrate in association with the porous region.

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In response, Isaka teaches that in forming a matrix on the semiconductor substrate by forming a mask, any number of desired patterns, i.e. differing lengths or depths, linear, circular, on a surface of the semiconductor substrate can be created; just as any number of channels, i.e. two channels or porous regions, may be inherently disposed onto the microchannel element. Isaka also, indeed, teach a detector associated with the porous regions in the separation device. The fabrication of the detector onto the substrate of the device would have only entailed an obvious design choice. For that reason, it is viewed that the claims, as amended, are inherently anticipated by Isaka.

b) Applicant argues that Isaka fails to disclose "binding a capture substrate to a matrix" because the enzyme disclosed in Isaka is not a capture substrate in that it reacts by detectably altering the substrate.

Contrary to Applicant's argument, Isaka, indeed, teach a capture substrate in column 3, lines 6-14 and only exemplifies an enzyme to be immobilized in the porous channel to carry out various reactions. Further, in capturing an analyte, the capture substrate necessarily reacts and "detectably alters (by binding)" the analyte. For that reason, the capture substrate in the instant invention is fully disclosed and exemplified in the disclosure of Isaka.

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c) Applicant argues that the combination of Isaka and Miura neither teach nor suggest fabricating a processor on the substrate. Applicant further argues that Isaka and Miura neither teach nor suggest a memory device in association with the separation device.

In response, Miura indeed teach a processor in communication with a detector disposed in the separation device. A processor necessarily and inherently contains, therewith, a memory element to be fully functional. Further, fabrication of the processor onto the substrate of the device would have only entailed an obvious design choice.

d) Applicant argues that Miura fails to teach or suggest a vacuum source that is in operative communication with the column chromatograph and that Miura only suggests the use of positive pressure to facilitate movement of sample.

In response, Miura et al., indeed, teach and suggest a migration facilitator comprising a vacuum source including a pump that is fed under positive pressure into the feed pump to facilitate movement of the sample such as taught in Applicant's disclosure in page 13, lines 23-30 of the specification. Specifically, a valve is connected to a first end of the flow path in the sample application area where the sample is selectively introduced then a carrier gas is fed under pressure by a feed pump and then discharged from a drain after having passed through the flowpath.

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e) Applicant argues that Wang fails to teach or fairly suggest inclusion of a thermal detector, field effect transistor, or a current detector specifically on a substrate where the column chromatography is formed and a vacuum source that is operatively in communication with an end of the chromatography column because the vacuum in Wang is only used to vary pressure within the chamber.

Contrary to Applicant's argument, Wang et al., indeed, disclose the thermal conductivity detector as being integrated into the separation column (see column 10, line 60 to column 11, line 33). Further, Wang et al., indeed, disclose the migration facilitator as including a valve for venting or purging gasses from a closed cavity, a vacuum (or near vacuum) source for use in altering the concentration of gas within a cavity in the separation column such as taught in Applicant's disclosure in page 13, lines 23-30 of the specification.

f) Applicant argues that Turner et al. qualifies as prior art under 35 USC § 102 (e) but does not properly qualify as prior art under 35 USC § 103(c).

In response, any prior art that qualifies under 35 USC § 102, whether the requirements encompass 35 USC § 102 (b) or 35 USC § 102 (e) such as in the case of Turner et al., follows and qualifies under 35 USC § 103(c).

15. No claims are allowed.

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16. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday to Thursday from 7:00 AM to 4:30 PM. The examiner can also be reached on alternate Fridays from 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

G. Gabel 2/12/01

Gailene R. Gabel
Patent Examiner
Art Unit 1641

Long V. Le

LONG V. LE
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